Current vaccines prequalifification procedure

Rationale for revision

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Outline of presentation

- Conceptual description of the WHO prequalification procedure
  - Purpose
  - Principles
  - Pre-conditions for submission
  - Procedure

- Challenges/rationale for revision

- Process for the revision of the PQ procedure
PURPOSE OF THE PQ PROCEDURE

A service provided to UN purchasing agencies. Provide independent opinion/advice on the quality, safety and efficacy of vaccines for purchase. Ensure that candidate vaccines meet WHO recommendations and are suitable for the target population, at the recommended schedules with appropriate concomitant products and meet the needs of the programme. Ensure continuing compliance with specifications and established standards of quality.

PRINCIPLES

- GMP
- Clinical data
- Consistency of final product characteristics
- Meeting WHO requirements and tender specs
- Reliance on NRA of exporting country
PRINCIPLES (cont)

Reliance on the NRA of the exporting country

- NRA must be functional as a result of evaluation against the WHO assessment tool
- Functionality status needs to be sustained
- Vaccine needs to be licensed by the NRA
- Continued regulatory oversight by NRA is required as well as communication with WHO about potential problems with the vaccine

Pre-conditions for submission

- Vaccine is licensed by the responsible NRA (Scientific opinion by EMA accepted)
- WHO guidelines/recommendations available
- Listed in the vaccine priority list (low priority vaccines may be postponed, non-priority vaccines will not be accepted for evaluation)
PROCEDURE
Last revised in 2005 (WHO/IVB/05.19)

- Scientific and technical review of a Summary dossier (Product Summary File)
- Testing of final product characteristics
- Consultation with NRA of exporting country
- Audit of manufacturing facilities (jointly with NRA)

Vaccines prequalified by WHO: Status 2010 (assured quality)

- 15 industrialized country mfrs
  - Australia
  - Belgium
  - Canada
  - Denmark
  - France
  - The Netherlands
  - Germany
  - Hungary
  - Italy
  - Japan
  - Rep. of Korea
  - Switzerland
  - Sweden
  - United Kingdom
  - USA

- 7 emerging economy country mfrs
  - Brazil
  - Bulgaria
  - Cuba
  - India
  - Indonesia
  - Russia
  - Senegal

- 24 manufacturers
  - 36 Sites

- 106 pre-qualified vaccines

- used in 124 countries

- 64% global population
Challenges

- Demand for vaccines PQ has increased in quality, quantity and complexity and present trend continues
  - Novel vaccines and new combinations available
  - Many vaccines in research pipeline
  - New financing mechanisms accelerate introduction
  - Increased complexity of products
  - Availability of new production technologies
  - Multiple production sites and partnerships between developing and industrialized country manufacturers
  - Challenges for regulatory oversight
Challenges

- Stakeholders are becoming more and more diverse, many different expectations
- Manufacturers from countries which have never supplied UN before may be submitting vaccines for evaluation shortly
- Need to better define programmatically acceptable product characteristics
- While expectations and demand have increased, PQ resources likely to remain stable

Revision of vaccines PQ procedure

An ad hoc committee on vaccines pre-qualification has been convened (19-21 April 2010)

Proposed revision addresses technical, policy and communication matters.

Includes presenting to the ad-hoc committee on vaccines prequalification with two "note for guidance" documents that have been produced (i.e. environmental monitoring and evaluation of clinical data for PQ purposes)
Process for the revision of the vaccines PQ procedure

WG1: Programmatic Suitability of Vaccines
WG2: Comparison between the different WHO PQ procedures
WG3: New approaches to testing
WG4: Streamlining of the PQ procedure for products with CHMP positive scientific opinion
WG5: Establishment of maturity levels for NRAs
WG6: Format and contents of file
  Approach to reassessments, review of updates and responses
WG7: Feasibility of streamlining the PQ procedure (risk based approach)
WG8: Regulatory oversight of vaccines manufactured in multiple sites/countries

WHITE PAPERS

SAGE’s 13-15 April 2010 for comments
Proposals for revision

Ad-Hoc Committee on Vaccines Prequalification
19-21 April 2010
Process for the revision of the vaccines PQ procedure

Ad-Hoc Committee on Vaccines Prequalification
19-21 April 2010

Recommendations

WHO-PQ Secretariat ➔ Develop revised draft procedure by 31st May 2010

Publication on website for comments until 30 June 2010

Final draft procedure by 31st July 2010

Presentation at ECBS 18-22 October for endorsement ➔ Final version revised procedure ➔ Submission to Executive Board May 2011 for final approval

THANK YOU

QSS/IVB/ND, 19 April 2010